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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,737	01/03/2007	Stephane Rioux	484112.436USPC	4671

500 7590 12/31/2009

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EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
12/31/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,737	RIOUX ET AL.	
	Examiner	Art Unit	
	Padma V. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,38-42,49 and 50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,38-42,49 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/23/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/23/09 has been entered.

2. The amendment filed on 10/23/09 is acknowledged and entered.

Status of claims

3. Claims 1-22, 24-37 and 43-48 have been cancelled
New claims 49-50 have been added.
Claims 23 and 38-42 have been amended
Claims 23, 38-42 and 49-50 are under examination as drawn to an elected invention.

Information Disclosure Statement

4. The Information Disclosure Statement submitted on 10/23/09 is acknowledged and a signed copy of the same is attached to this Office action.

Claim Rejections - 35 USC 112, first paragraph maintained

5. The rejection of claims 23, 38, 40 , 42 and 49-50 under 35 U.S.C. 112, first paragraph is maintained as set forth in the previous office action.

Applicant cintinues to argue 10/23/09 that instant claims satisfy the written description requirement and the sequence that is 90% or 95 % identical to SEQ.ID.NO:2 and fragments as claimed have been disclosed in the specification , pages 16, 18, 19, 48-54. Applicant states that Table 2 and example 1 show that the SHB-GAS-102 polypeptide is a conserved polypeptide expressed by different serotype strains of S. *pyogenes (see, e.g.,* page 48, line 19 through page 54, line 4 and Tables 2 and 3 (Example 1)) . The polypeptide has a structure that consists of an amino acid sequence at least 90% identical to SEQ ID NO:2 or that comprises an amino acid sequence at least 95% identical to the amino acid sequence set forth as SEQ ID NO:2. Thus, the present application has described that the structure of

the polypeptides of the claimed pharmaceutical compositions differs by only 5-10% from the amino acid sequence of SEQ ID NO :2 *(see, e.g.,* 24, lines 25-27). Substitutions, if any, are those that have a minimal influence on the secondary structure and hydropathic nature of the polypeptide such that the polypeptide retains immunogenicity *(see, e.g.,* page 23, lines 15-29; page 26, lines 28-31). By describing the full-length sequence and defining the percent identity of polypeptides included in the claimed pharmaceutical compositions, the specification describes in sufficient detail the structure of the polypeptides, conveying to a person skilled in the art that Applicants possessed the claimed embodiments at the time of filing. In addition, by providing the detailed chemical structure, that is, the amino acid sequence *(i.e.,* SEQ ID NO:2), the present application therefore discloses the structure of polypeptide fragments consisting of 15 or more amino acids of SEQ ID NO:2 *(e.g.,* page 19, line 13 through page 20, line 13; page 29, lines 8-10; Figure 2). Further applicant states that Working example 8 and 9 show that SEQ ID NO:2/ SHB-GAS 102 induces antibody response and animals were protected against challenge upon passive immunization of antibodies.

Applicants arguments are fully considered but havenot been found persuasive because the specification on pages 48-54 and Tables 2 and 3 show that the full length polypeptide SEQ ID NO: 2 has been used to raise antisera and said antisera is been used to identify other strains of *S.pyogenes*. However, the specification fails to provide which strains differ by only 5-10% from the amino acid sequence of SEQ ID NO: 2. Additionally the specification fails to show that antisera raised against polypeptides that differ by 5-10% or fragments having 15 contiguous amino acids from the amino acid sequence of SEQ ID NO: 2 is able to identify what other strains of *S.pyogenes*. Thus, the application fails to provide even a single species of the genus SEQ ID NO: 2 that induce an immune response against (i.e., protect) all strains of *S.pyogenes*.

It is noted that SEQ.ID.NO:2/ SHB-GAS 102 has been shown to induce antibodies and said antibodies protected animals upon transfer of antibodies . However, the claimed variant polypeptides would induce antibodies that protect all *S. pyogene* strains is missing from the disclosure . Further, the specification fails to correlate the structure /function relationship of an isolated polypeptide that is 90% or 95% identical to SEQ.ID.NO:2 or fragments to induce an immune response against *S. pyogenes* as argued by the applicant .

6. The enablement rejection of claims 23, 38, 40 , 42 and 49-50 under 35 U.5.C. 112, first paragraph is maintained as set forth in the previous office action.

Applicant argues that a person skilled in the art knows how to make fragments without loss of function and cites references of reccord. Applicant also argues that the references cited by the examiner fail to reflect the predictability associated with identifying functional polypeptide variants (page 12 in particualr) Applicants arguments are fully considered but has not been found persuasive because none of the cited art indicate that the antibodies generated to a variant peptide will bind to full length SEQ ID NO:2/ SHB-GAS 102 and induce an immune response

(protective) against S. *pyogenes*. It is noted whether the claimed induces an antibody which can recognize and bind to the full length polypeptide and at the same time induce a protective immune response against *S. pyogenes*. The cited references by the examiner in the previous Office action indicated that it is not predictable to induce an antibody against fragment that can bind to the full length polypeptide . Since these antibodies have not been shown bind to the polypeptide , one skilled in the art understands that the antibodies are not immunoreactive and is unpredictable to use them in an immunogenic composition that induces immune response against S. pyogenes In view of applicant's specification and the prior art cited by the examiner and applicant, it would require undue experimentation on the part of the skilled artisan to use the broadly claimed pharmacutical composition

Applicant states that petide immunogens have been used to induce protective immunity and cites Pinchuk et al and McGuire et al (page 12). The examiner reviewed the art and found that Pinchuk et al teach about cytotoxic T-cell response to one strain of Chlamydia .The cited art does not teach that an isolated polypeptide having 90% or 95% identity or fragments of said polypeptide induce protective immune response against *genus Chlamydia*. McGuire et al teach that homogenate and peptide antigens were found to be protective, however the art does not teach peptides alone induce protective immunuty .

7. The rejection of claims 23, 38-42 and 49-50 under 35 U.S.C. 102(b) as being anticipated by Telford J et al WO200234771 is maintained for the same reasons as set forth in the previous Office action

Applicant argues that Telford fails to teach or suggest an imminogenic composition as claimed because the cited reference teaches hundreds of full-length polypeptides and the polypeptide as claimed.

Applicants arguments are fully considered but has not been found persuasive because Telford et al clearly disclose a polypeptide , SEQ.ID.NO:6346 which is 100% identical to the claimed polypeptide in addition to several hundreds of full-length polypeptides that induce an immune response to S.pyogenes because the polypeptide is obtained from S.pyogenes.

Applicant states that Telford provides more than 5,000 open reading frames that putatively encode polypeptides that are expressed by S. pyogenes and provides no more than a generalized statement with respect to how the various putatively encoded polypeptides disclosed therein may be used. Telford describes that each and every one of the polypeptides disclosed therein may be a useful antigen for a vaccine or a diagnostic. Given that only a few S. pyogenes antigens have been investigated as viable vaccine candidates (see, e.g., specification at page 1, line 30 through page 2, line 20), a person skilled in the microbiology and vaccine arts would immediately understand that the statement in Telford provides no guidance with respect to which polypeptides disclosed therein may be capable of inducing an immune response against S. pyogenes.

Applicants arguments are fully considered but has not been found persuasive because Telford provides more than 5,000 polypeptides with structure, however, one such polypeptide was SEQ.ID.NO:6346 (Example 2053, page 2320 in the patent) that can be used for vaccine purposes. Given that the prior art fully discloses the polypeptide from *S.pyogenes*, one skilled in the microbiology and immunology art knows how to formulate the immunogenic composition comprising said polypeptide to induce an immune response. Again , products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable.

Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

8. No claims are allowed.

9. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 156, 1989. The Right Fax number is 571-273-8300.
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272 0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571) 272-0956.

Respectfully,
/Padma Baskar /
Examiner, Art Unit 1645

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645